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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/935,366

08/22/2001

J. Fernando Bazan

15631-0004801US

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10/30/2002

DNAX RESEARCH, INC.  
LEGAL DEPARTMENT  
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EXAMINER

MURPHY, JOSEPH F

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 10/30/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n N .

09/935,366

Applicant(s)

BAZAN, J. FERNANDO

Examin r

Joseph F Murphy

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1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7, 9, 10 and 12-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-10, 12-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## **DETAILED ACTION**

### ***Formal Matters***

The finality of the last Office action is withdrawn, and new grounds of rejection are set forth below. Claims 1-7, 9-10, 12-17 are pending and under consideration.

### ***Response to Amendment***

The rejection of claims 1-7, 9-10, 12-17 under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed patentable utility has been withdrawn based on the showing that IL-B30 is differentially expressed in a number of immune active cells (Column 34, lines 35-41).

### ***Claim Rejections - 35 USC § 112 first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 9-10, 12-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid encoding an amino acid of SEQ ID NO: 2, 4 or 5 or a nucleic acid with the sequence as set forth in SEQ ID NO: 1, 3, does not reasonably provide enablement for a nucleic acid encoding 132 contiguous amino acids of SEQ ID NO: 2, or 17 contiguous amino acids of SEQ ID NO: 4, or 30 contiguous amino acids of SEQ ID NO: 5, or a nucleic acid which hybridizes to SEQ ID NO: 1 or 3 or a nucleic acid encoding an antigenic polypeptide of ILB-30 comprising 132 contiguous amino acids of SEQ ID NO: 2, or 17 contiguous amino acids of SEQ ID NO: 4, or 30 contiguous amino acids of SEQ ID NO: 5, or a nucleic acid which hybridizes to SEQ ID NO: 1 or 3. The specification does not enable any

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person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 1-7, 9-10, 12-17 are overly broad since insufficient guidance is provided as to which of the myriad of variant nucleic acids encode polypeptides which will retain the characteristics of an ILB-30 polypeptide or of being antigenic polypeptides of ILB-30. Applicants do not disclose any actual or prophetic examples on expected performance parameters of any of the possible muteins of ILB-30, and there is no correlation between the antigenicity of the ILB-30 polypeptide and its structure. It is known in the art that even single amino acid changes or differences in the amino acid sequence of a protein can have dramatic effects on the protein's function. It is also known in the art that a single amino acid change in a protein's sequence can drastically affect the structure of the protein and the architecture of an entire cell. For example, Voet et al. (1990) teaches that a single Glu to Val substitution in the beta subunit of hemoglobin causes the hemoglobin molecules to associate with one another in such a manner that, in homozygous individuals, erythrocytes are altered from their normal discoid shape and assume the sickle shape characteristic of sickle-cell anemia, causing hemolytic anemia and blood flow blockages (pages 126-128, section 6-3A and page 230, column 2, first paragraph).

Since the claims encompass nucleic acids encoding variant proteins and given the art recognized unpredictability of the effect of mutations on protein function, it would require undue experimentation to make and use the claimed invention. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. The test of enablement is not whether any experimentation is necessary, but

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whether, if experimentation is necessary, it is undue. The factors considered to be relevant in the instant case are set forth below:

(1) the breadth of the claims - The claims are drawn to a nucleic acid encoding an antigenic polypeptide of ILB-30 comprising 132 contiguous amino acids of SEQ ID NO: 2, or 17 contiguous amino acids of SEQ ID NO: 4, or 30 contiguous amino acids of SEQ ID NO: 5, or a nucleic acid which hybridizes to SEQ ID NO: 1 or 3.

(2) the nature of the invention - The instant invention is a nucleic acid encoding an antigenic polypeptide of ILB-30 comprising 132 contiguous amino acids of SEQ ID NO: 2, or 17 contiguous amino acids of SEQ ID NO: 4, or 30 contiguous amino acids of SEQ ID NO: 5, or a nucleic acid which hybridizes to SEQ ID NO: 1 or 3.

(3) the state of the prior art - The Voet reference demonstrates that even single amino acid changes or differences in the amino acid sequence of a protein can have dramatic effects on the protein's function.

(5) the level of predictability in the art - The Voet reference demonstrates the unpredictability of the protein art.

(6) the amount of direction provided by the inventor - Applicant has only taught a nucleic acid with a sequence as set forth in SEQ ID NO: 1 and 3, and the polypeptide of SEQ ID NO: 2, 4 and 5. The Specification does not disclose any correlation between the antigenicity of the ILB-30 polypeptides and their structure.

(7) the existence of working examples - Working examples are not provided for ILB-30, or antigenic polypeptides of ILB-30.

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(8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. Given the breadth of claims 1-7, 9-10, 12-17 in light of the predictability of the art as determined by the number of working examples, the level of skill of the artisan, and the guidance provided in the instant specification and the prior art of record, it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention.

Claims 1-7, 9-10, 12-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

These are genus claims. The claims are drawn to a nucleic acid encoding an antigenic polypeptide of ILB-30 comprising 132 contiguous amino acids of SEQ ID NO: 2, or 17 contiguous amino acids of SEQ ID NO: 4, or 30 contiguous amino acids of SEQ ID NO: 5, or a nucleic acid which hybridizes to SEQ ID NO: 1 or 3. The specification and claim do not indicate what distinguishing attributes shared by the members of the genus. The specification and claim do not place any limit on the number of amino acid substitutions, deletions, insertions and/or additions that may be made to the encoded SEQ ID NO: 2, 4 or 5. The Specification does not disclose any correlation between the antigenicity of the ILB-30 polypeptides and their structure. Thus, the scope of the claim includes numerous structural variants, and the genus is highly

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variant because a significant number of structural differences between genus members is permitted. The specification and claim do not provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, a nucleic acid with a sequence as set forth in SEQ ID NO: 1 or 3 and the polypeptide of SEQ ID NO: 2, 4 and 5 are insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

***Claim Rejections - 35 USC § 112 second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16 is indefinite in the recitation of the term "natural sequence". It is unclear whether this term imposes a required limitation on the claim, such that it only encompasses, for example, polynucleotides amplified from human cDNA, or only sequences produced by digestion with restriction enzymes of DNA isolated from tissue which contains polynucleotides



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encoding the polypeptide, or if the claim encompasses all polynucleotide sequences that encode the polypeptide. Therefore, the metes and bounds of the claim are unclear.

Claims 1 and 16 are vague and indefinite in the recitation of the term "mature". It is not clear whether this imposes a required limitation on the claim, such that the nucleic acid must have actually encoded a polypeptide which was post-translationally modified, or only encodes a polypeptide which could be post-translationally modified, and it is not clear what the post-translational processing would have to be. Claims 3-10, 12-15 and 17 are rejected insofar as they depend on the recitation in claims 1 and 16 of "mature".

Claims 1 and 4 are vague and indefinite because it is not clear whether the encoded amino acid sequence must serve as the antigenic polypeptide, thus no function has been set forth for the encoded peptides. Claims 2-3, 5-17 are rejected insofar as they depend on claims 1 and 4.

### ***Conclusion***

No claim is allowed.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Joseph F. Murphy, Ph. D.  
Patent Examiner  
Art Unit 1646  
October 21, 2002



DAVID S. ROMEO  
PRIMARY EXAMINER